CONFIDENTIAL

K970304

SUMMARY OF SAFETY AND EFFECTIVENESS

Dynflex Part Material Change 510(k) Notification

APR 11 1997

I. SUBMITTER

Name and Address:	American Medical Systems 10700 Bren Road West Minnetonka, Minnesota 55343
Phone and Fax Numbers:	612/930-4666 Main Number 612/930-6293 Office Number 612/930-6496 FAX
Contact Person:	Dennis Toussaint
Date of Summary Preparation:	December 30, 1996
Establishment Registration Number:	2183959

II. DEVICE NAME

Device Common or Usual Name:	Penile Inflatable Implant
Device Trade or Proprietary Name:	AMS Dynaflex® Penile Prosthesis
Classification Name	Penile Inflatable Implant (21 CFR 876.3350)

III. PREDICATE DEVICE

Penile Inflatable Penile Prosthesis (21 CFR 876.3350)

IV. DEVICE DESCRIPTION

Except for the material used to produce several prosthesis parts changes, the Dynaflex penile prosthesis description does not change.

V. INDICATIONS FOR USE

The indications for use do not change for this modification.

K970304
2 of 2

VI. COMPARISON TO PREDICATE DEVICES

The materials used to produce several prosthesis part changes, similar to corresponding parts used to produce the Ambicor penile prosthesis. Otherwise, Dyanflex devices with new part materials are identical in specifications, performance, manufacture, packaging and sterilization to Dynaflex devices in commercial distribution.

VII. INFORMATION THAT SUPPORT THE MATERIAL CHANGES

Material and biocompatiblity testing was used to evaluate parts made with the new materials. Acceptance criteria were established for each test. Analysis of all test results indicated that each acceptance criterion was met. These findings supported the safety and effectiveness of Dynaflex parts made with the new materials.

VIII. CONCLUSIONS

It was concluded that Dynaflex prostheses with parts made with the new materials were substantially equivalent to predicate Dynaflex and Ambicor prostheses. Material and biocompatibility testing demonstrated that parts made with the new materials were safety and effective.